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April 16, 2012

VIA HAND DELIVERY

Headquarters Hearing Clerk (1900L)
United States Environmental Protection Agency
Office of Administrative Law Judges
1200 Pennsylvania Avenue NW
Washington, DC 20450

Re: In the Matter of Elementis Chromium, LP
Docket No. TSCA-HQ-2010-5022

Dear Ms. Anderson:

This firm represents Elementis Chromium Inc. (formerly Elementis Chromium, LP) in the above matter. Enclosed please find an original and two (2) copies of *Respondent's Initial Post-Hearing Brief* and *Proposed Findings of Fact, Proposed Conclusions of Law and Proposed Order*. Please file the originals of these documents and return one time-stamped copy of each in the enclosed self-addressed stamped envelope.

Please call me if you have any questions. Thank you for your attention to this matter.

Very truly yours,

Ronald J. Tenpas

Enclosure

cc: Hon. Susan L. Biro, Chief Administrative Law Judge, USEPA (via Hand Delivery)
Mark A.R. Chalfant, Esq., USEPA (via email and FedEx)
Erin K. Saylor, Esq., USEPA (via email and FedEx)

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

IN THE MATTER OF:	)	
	)	Docket No. TSCA-HQ-2010-5022
	)	
Elementis Chromium Inc.	)	
f/k/a Elementis Chromium, L.P.,	)	
	)	
	)	
Respondent.	)	
	)	

INITIAL POST-HEARING BRIEF OF RESPONDENT, ELEMENTIS CHROMIUM INC.

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CX 45 "Agreement for Consulting Services," between the Industrial Health Foundation, Inc. and Applied Epidmiology, Inc., dated March 1, 1998, regarding consulting services for proposed

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Respondent, Elementis Chromium Inc.1 ("Respondent" or Elementis"), respectfully submits this Initial Post-Hearing Brief pursuant to the Presiding Officer's Post-Hearing Scheduling Order.

I. INTRODUCTION

The United States Environmental Protection Agency ("Complainant" or "EPA" or "the Agency") brought this enforcement action against Elementis for an alleged violation of Section 15(c) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2614(c). EPA alleges that Elementis was required by Section 8(e) of TSCA to submit to EPA the *"Collaborative-Cohort Mortality Study of Four Chromate Production Facilities, 1958-1998, Final Report"* prepared by Applied Epidemiology dated September 27, 2002 (the "Final Four Plant Report"). EPA claims that the Report contains information which reasonably supports the conclusion that hexavalent chromium presents a substantial risk of injury to health or the environment, and such information was not previously known by EPA.

A hearing was held before the Presiding Officer on December 12–14, 2011 in Washington, DC. The hearing evidence demonstrated that the Final Four Plant Report identified a substantial risk associated with certain high cumulative exposures to hexavalent chromium, but that (a) EPA already knew of the risk associated with such high cumulative exposures and (b) Elementis knew that EPA was aware of the risk. Thus, Elementis had no obligation to provide the Final Four Plant Report to EPA.

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[1] Elementis Chromium LP was merged into Elementis Chromium GP Inc. on September 10, 2010. Elementis Chromium GP Inc. then changed its name to Elementis Chromium Inc.

II. SUMMARY OF ARGUMENT

Elementis acknowledges that it is a manufacturer and distributor of chromium chemical products, including some that contain hexavalent chromium, and that it received the Final Four Plant Report on October 8, 2002. Nor does Elementis assert that it submitted the Final Four Plant Report to EPA prior to November 17, 2008, when it promptly submitted it in response to an EPA subpoena that, for the first time, gave Elementis any indication that EPA might consider the Four Plant Report to be reportable under TSCA 8(e). But none of this matters.

The hearing evidence established that Elementis was not required to submit the Final Four Plant Report to EPA under TSCA Section 8(e). The evidence shows that the only information in the Final Four Plant Report reasonably supporting the conclusion that hexavalent chromium presents a substantial risk of injury to human health was the finding that there was a statistically significant increased incidence of lung cancer in the plant employees who had been exposed to high cumulative levels of hexavalent chromium. But such an increased incidence of lung cancer in persons exposed to high cumulative levels of chromium had been found in prior epidemiologic studies known to EPA (including one that was actually *funded* by EPA), and Elementis had actual knowledge that such studies were in EPA's possession. Indeed, the evidence demonstrated that EPA's own earlier study had demonstrated an increased risk of cancer at cumulative exposure levels lower than at the levels where this risk emerged in the Final Four Plant Report. Thus, there was nothing new in a study, such as the Final Four Plant Report, that showed risk at higher cumulative exposure levels.

The evidence in this matter further demonstrates that when Dr. Joel Barnhart, Vice President-Technical for Elementis, received the draft Final Four Plant Report from

Applied Epidemiology in April 2002, he analyzed the Report, and determined that its reasonably supportable conclusions related to risk did not differ from prior epidemiologic studies with which he was already familiar. This included, especially, the study, completed just two years prior to the Final Four Plant Report, paid for with EPA funds, and conducted by Dr. Herman Gibb (the "Gibb Study"). Dr. Gibb, at the time of the study, had risen to the senior ranks within EPA, having long been the Agency's leading expert with respect to risks associated with hexavalent chromium. Dr. Barnhart testified that he knew that EPA already had the Gibb Study in its possession, and, therefore, determined that there was no obligation to provide the Report to EPA pursuant to Section 8(e).

Moreover, Dr. Gibb himself testified in Elementis's support. Dr. Gibb, a former top toxicologist at EPA, who had studied the effects of occupational exposure to hexavalent chromium for much of his career, explained that while he was at EPA, he conducted a large, perhaps the largest, epidemiological study of worker exposure to hexavalent chromium. That study ultimately earned Dr. Gibb a major agency award, given in recognition that his study was "the most significant and detailed study of the lung cancer and clinical irritation risks from chromium ever conducted." Dr. Gibb testified that the study he conducted, which was published in 2000, two years prior to the Final Four Plant Report, showed risk from hexavalent chromium at much lower exposure levels than was shown in the Final Four Plant Report. Moreover, Dr. Gibb testified that the Final Four Plant Report is merely corroborative of existing information known to EPA on the substantial risk associated with hexavalent chromium -- in short, the Final Four Plant Report adds nothing new.

In an effort to maintain this enforcement action in the face of facts that clearly establish that Elementis did not violate Section 8(e), EPA presented several witnesses at hearing who were not qualified to opine regarding substantial health effects from hexavalent chromium. Those witnesses, while qualified as general epidemiologists or heath assessors, had very little experience, -- and, in some instances, no experience -- with studying hexavalent chromium in the occupational setting. Nonetheless, EPA's witnesses testified that the Final Four Plant Report contained "new" information about hexavalent chromium because the worker exposures in the plants were long-term, low intensity exposures, and the exposures in the Gibb Study were short-term, high-intensity exposures. That claim, that the reason the Final Four Plant Report needed to be submitted is because of the alleged differences it had in the intensity of worker exposure, has become the sole basis on which EPA now maintains its claim.

Putting aside the question of whether a claim passes pleading muster when rooted in such imprecise and ill-defined terms as "low intensity" and "high intensity," "short term/long term," the Agency's argument fails both as a matter of fact and law for multiple reasons. First, whatever might have been the manner in which workers were exposed (low intensity/long term v. high intensity/short term), the witnesses – including EPA's own experts – routinely acknowledged that the critical and appropriate starting point for performing the epidemiological risk analysis in Gibb and the Final Four Plant Study was to work from cumulative total exposure. Thus, the Agency in focusing on the alleged differences in exposure intensity both at the hearing and in its post-hearing memorandum at best points out an irrelevant distinction between the two studies, given the fact that it is cumulative total exposure that is relevant in assessing risk, and identical

cumulative exposures can result from multiple exposure scenarios. On this point, a point EPA's own experts acknowledged as the relevant point – at what cumulative total exposure does a statistically significant cancer risk emerge – the Final Four Plant Study provided no new information. It is as if, in comparing two studies of the vision of two different worker cadres, a critic pointed out that one group had more brown haired people while the second had more blondes. Even if true, that fact would be of no consequence to determining whether the second study presented new vision information, where all experts agreed that the way to measure vision does not turn on hair color. So too here – the experts agree that cumulative exposure, also sometimes called cumulative dose, is the basis on which to study and understand cancer risk associated with hexavalent chromium exposure. And as to this appropriate and conventional risk metric, the Final Four Plant Study provided no information that Gibb had not already established.

Second, on their face, neither the Final Four Plant Report nor the Gibb Study reported any increased risk information in which the risk was correlated to the high intensity/short duration or low intensity/long duration on which EPA now plants its flag. Thus, EPA's position relies not on what the Final Four Plant Report actually reports, but on what EPA believes it might be read to suggest based on further manipulation, evaluation and interpolation. But that is not the standard on which TSCA 8(e) requires reporting. To read 8(e) as requiring companies to report in any circumstance where the Agency might imagine a use for the report that through further analysis might show some risk that the report itself does not, is to read the Section 8(e) provision out of existence. No company could ever have confidence that a report it received could never be subject

to such further interpretation that would turn a corroborative report into reportable risk information.

Third, the factual premise on which EPA relies – that the Final Four Plant Report involved only low exposure/long term employees and the Gibb Study the converse, is not, in fact, supported by the data provided in the Final Four Plant Report or the Gibb Study. In turn, EPA's attempts to salvage this ill-advised enforcement action by creating unsupportable findings purportedly rooted in the Final Four Plant Report and the Gibb Study cannot succeed.

In sum, the record in this matter is clear:

1) at the time Elementis received the Final Four Plant Report, EPA was fully aware of information that exposure to high levels of hexavalent chromium, on a cumulative basis, increases the risk of contracting lung cancer, 2) at the time Elementis received the Final Four Plant Report, Elementis had actual knowledge that this information was known to EPA, and 3) this was the only information in the Final Four Plant Report which reasonably supports the conclusion that hexavalent chromium presents a substantial risk of injury to health. Therefore, the only possible conclusion is that Elementis had no obligation to provide the Final Four Plant Report to EPA. Accordingly, the Presiding Officer should determine that Elementis did not violate Section 8(e) of TSCA, and this enforcement action should be dismissed.

III. STATEMENT OF FACTS[2]

It has been well known for at least 60 years that hexavalent chromium is a human carcinogen. Tr. at 1034 (Gibb). Following World War II, several studies of United

[2] This Statement of Facts section focuses on those facts most essential to the ultimate legal questions presented in this matter. Further facts are discussed in the argument section as necessary to provide additional detail or useful context to the arguments that then follow.

States chromate production workers reported an increased risk of lung cancer over the risk faced by the general population. CX 62 at 2. In 1984, EPA itself determined that there was a linear relationship between airborne exposure to hexavalent chromium and the risk of lung cancer. RX 25 at 27. In 2000, Dr. Herman Gibb, the Assistant Center Director for the National Center for Environmental Assessment within EPA, published an EPA-funded study in the American Journal of Industrial Medicine, based on a cohort of 2,357 workers at a chromate production plant in Baltimore, Maryland. CX 62 at 1. The Gibb Study concluded that certain levels of cumulative hexavalent chromium exposure was associated with an increased lung cancer risk. CX 62 at 1; Tr. at 1037 (Gibb).

In 1998, the Chromium Chemicals Health and Environmental Committee (the "Chromium Committee") of the Industrial Health Foundation ("IHF") retained Applied Epidemiology to conduct an epidemiologic study of chromium workers at five chromium manufacturing facilities. CX 45. Elementis, along with Occidental Chemical Corporation ("Occidental") and Bayer AG ("Bayer") were the industry members of the Chromium Committee at the time Applied Epidemiology was retained. Tr. at 649 (Mundt); Tr. at 964 (Barnhart). The five plants proposed for the study were owned and operated by the three member companies, with one being owned by Occidental (Castle Hayne, North Carolina), two being owned by Bayer (Leverkusen and Uerdingen) and two being owned by Elementis (Corpus Christi, Texas and Eaglescliffe, England).[3] Tr. at 653-654 (Mundt); CX 45 at 11-22.

In commissioning the epidemiologic study, the Chromium Committee was interested in determining whether process changes that had been implemented for a

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[3] In 1999, it became apparent that the data from Elementis' Eaglescliffe, England plant would not be compiled in time to be included in the study. This plant was thus eliminated from the study, resulting in just four plants in the study. Tr. at 967-968 (Barnhart).

sufficiently long time in each of the plants had resulted in any difference to the risk of lung cancer previously seen in the chromium manufacturing industry. Tr. at 648, 653 (Mundt). Specifically, the study was to analyze whether the process changes had resulted in lower lung cancer risk to the workers in these plants, primarily due to the reduction in respiratory exposure to hexavalent chromium as a result of those changes. Tr. at 648, 653 (Mundt). Such a change had the potential to have decreased chromium exposures for such workers. Tr. at 653.

From 1998 to 2002, Dr. Kenneth Mundt of Applied Epidemiology conducted the study requested by the Chromium Committee and in October 2002 produced the Final Four Plant Report providing his findings. RX 12, CX 1. Applied Epidemiology's study found that only those workers who fell into the highest group of cumulative exposure showed an increased risk of lung cancer when compared to the general population. Tr. at 698, 737-742 (Mundt); CX 1 at 98. As detailed in the Final Four Plant Report and as Dr. Mundt explained at the hearing, the study revealed that only those workers whose total cumulative exposures were in the fourth quartile had a statistically significant increase in cancer risk. For this fourth quartile, i.e. those with exposure greater than 200 micrograms per liter years (a measure of exposure related to chromium levels found in urine), "there's roughly a doubling of the risk that is statistically significant." Tr. at 737 (Mundt). In sharp contrast, in the three other, lower exposure quartiles, the study did not find any statistically significant increase in the risk of lung cancer among the workers when compared to the general population. Tr. at 737-742 (Mundt). In summarizing his report, Dr. Mundt testified that "for all of the first three quartiles there's no indication of increased risk." Tr. at 737 (Mundt). He further testified, "[t]he majority of the data

where there's no exposure exceeding 200 micrograms per liter years shows no difference from the unexposed general population rates of lung cancer." Tr. at 741 (Mundt). Moreover, the study did not identify *any* increased risk of lung cancer in the workers at the Elementis plant located in Corpus Christi, Texas.[4] Tr. at 1042-1043 (Gibb). Put another way, the excess risk resulted almost entirely from a higher than normal cancer risk among the German plant workers, rather than those in the United States. Tr. at 923 (Mundt). In turn, this appeared to have occurred because, contrary to what had been casually understood going into the study, the process changes in the German plants were likely implemented over many years, in turn allowing higher cumulative exposures to some workers in the German cohort. Tr. at 997-998 (Barnhart).

Thus, the Final Four Plant Report confirmed what the industrial health community and, most importantly, EPA, already knew: higher cumulative exposure to chromium is associated with an increased risk to lung cancer. CX 1 at 89-90; Tr. at 1034, 1037 (Gibb). Further, the Final Four Plan Report offered nothing new concerning risks at the lower levels of exposure. This was for two reasons. First, as Dr. Mundt explained, for the lowest three quartiles, the Final Four Plant Study showed no increased risk at all when compared to a general population. Tr. at 737 (Mundt). In turn, as to those groups the study necessarily could not have revealed new "risk" information – instead, the study showed the absence of risk. Second, the cumulative exposure level at which risk was shown in the Final Four Plant Study was a cumulative exposure level much higher than the cumulative exposure level at which Dr. Gibb's study had already shown risk to be present, a fact Dr. Gibb confirmed through his own testimony, and a fact that the

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[4] The study also did not identify any increased risk of lung cancer at the other United States plant, the Occidental plant in Castle Hayne, North Carolina, which was purchased by Elementis in December 2002. Tr. at 1042-1043 (Gibb).

government's experts repeatedly acknowledged throughout trial. Tr. at 1076 (Gibb); Tr. at 1097-1098 (Speizer); Tr. at 436-440 (Clapp); Tr. at 241 (Cooper).

Applied Epidemiology's finding of elevated risk among the highest exposed workers in the two German plants, plants where there had been delays in process changes, was entirely consistent with findings of many prior epidemiologic studies, including the EPA-funded Gibb Study. Tr. at 1057 (Gibb). That is, given that the Final Four Plant Report showed a statistically significant increased risk of cancer to those in the highest exposure group and no such increased risk in the lower three exposure groups, the Final Four Plant Report simply corroborated that cumulative hexavalent chromium exposure was associated with an increased lung cancer risk. CX 62 at 1; Tr. at 1037 (Gibb).

Because the Chromium Committee members from all three companies were well aware of the known lung cancer risks associated with workers in chromium plants who experience high respiratory exposure to hexavalent chromium, the report provided to them absolutely no new information on the risk associated with hexavalent chromium. More importantly, because the companies also knew that EPA had knowledge of hexavalent chromium's risk profile, which the Applied Epidemiology study only confirmed, none of the companies, including Elementis, believed that the Final Four Report needed to be provided to EPA pursuant to Section 8(e) of TSCA. Tr. at 985-986 (Barnhart).

Dr. Joel Barnhart of Elementis testified that when he received the Final Four Plant Report in 2002, he was well aware of the Gibb Study, which was published in 2000. Tr. at 984 (Barnhart). Dr. Barnhart further testified that he had attended a presentation of the

Gibb Study by Dr. Gibb or one of his co-authors while it was being developed and knew that EPA had funded it and, therefore, that "EPA would be knowledgeable and know that it was going on." Tr. at 984 (Barnhart). Dr. Barnhart testified that given Dr. Gibb's employment with EPA at the time, he "believed that EPA had knowledge of the Dr. Gibb Study." Tr. at 985-986. EPA has not disputed that it had actual knowledge of the Gibb Study, nor plausibly could it, given that it paid for the study, Dr. Gibb was an EPA employee at the time he conducted the study, and EPA gave Dr. Gibb a major award, based on the study's importance. Tr. at 1027-1028 (Gibb).

Dr. Barnhart testified that he compared the Final Four Plant Report to the Gibb Study and concluded that the information was not something that needed to be reported because it was not different than the information EPA already had obtained through the Gibb Study. Tr. at 981-984; 990-991. Moreover, at the time he received the Final Four Plant Report, Dr. Barnhart was aware of the Mancuso study, which EPA used in its 1984 Health Assessment document to generate its cancer potency calculation. Tr. at 995 (Barnhart). Also, Dr. Barnhart knew from EPA's 1984 Health Assessment that EPA believed there was a linear relationship between risk of cancer and exposure to hexavalent chromium. Tr. at 995. By the time Dr. Barnhart received the Final Four Plant Report in 2002, he believed that "everyone working in the plants as well as the people working in the field of understanding the risks would say that the relationship is the greater the exposure, the higher the risk." Tr. at 996. As a result, Elementis did not feel the need to provide a report documenting what was already well-known to EPA and, for that matter, the chromium manufacturing industry.

Although the companies were not required to provide the Report to EPA pursuant to TSCA, Applied Epidemiology widely shared the Report's findings with independent reviewers, as well as with the epidemiology expert community. In fact, prior to providing the final Report to the Chromium Committee in October 2002, Applied Epidemiology presented the study's finding to an international conference of epidemiologists in Barcelona in September 2002. Tr. at 704-705 (Mundt).

The evidence presented at hearing unequivocally established that Elementis was not required to submit the Report to EPA under Section 8(e) of TSCA. The findings of the study, as detailed in the Final Four Plant Report, corroborated the well-known and well-established adverse health effects associated with hexavalent chromium. Under the express provisions of TSCA § 8(e) and EPA's own guidance, Elementis had no obligation to report the information under TSCA § 8(e).

IV. ARGUMENT

A. Elementis Was Not Required To Provide The Report To EPA Under Section 8(e) Of TSCA As Elementis Knew That The Substantial Risk Information In The Report Was Already Well Known To EPA.

Section 8(e) of TSCA is a one-sentence provision that reads as follows:

> Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information *unless such person has actual knowledge that the Administrator has been adequately informed of such information.*

15 U.S.C. § 2607(e) (emphasis added). Thus, in order to establish a violation of this provision, the following elements must be proven:

- Alleged violator is a person who manufactures, processes or distributes in commerce a chemical substance or mixture;

- Alleged violator obtains information that reasonably supports the conclusion that a chemical substance or mixture that it manufactures, processes or distributes in commerce presents a substantial risk of injury to health; and

- Alleged violator fails to immediately notify the Administrator of the information.

However, the statute also provides that a manufacturer, processor or distributor does not have to provide substantial risk information if such information was: a) known to the Administrator; and b) the alleged violator had actual knowledge that such information was known to the Administrator. It is, therefore, an absolute defense to an alleged TSCA Section 8(e) violation if the alleged violator shows that the substantial risk information was already known to EPA and the alleged violator knew this.

1. The Only Substantial Risk Information in the Report is the Finding That Persons Exposed to High Cumulative Levels of Hexavalent Chromium Have an Increased Risk of Lung Cancer.

The Applied Epidemiology epidemiological study analyzed workers at four chromium chemicals manufacturing plants, two of which were located in the United States, and two of which were located in Germany. CX 1 at 15. The first step in conducting the study was to collect exposure information from each of the plants. Tr. at 666-667 (Mundt). As Dr. Mundt testified, the two German plants, over their years of operations, had collected many urine samples from their workers and analyzed those samples for chromium levels. Tr. at 675-676 (Mundt). In addition, those plants had collected some air sampling data, from either personal air monitors or area samplers. CX 1 at 106, Tr. at 677 (Mundt). The American plants, one owned by Elementis, and one owned by Occidental Chemical Company, had collected only personal employee air monitoring samples and these were limited to certain time periods. CX 1 at 106, Tr. at 676.

Because the vast majority of the German plant exposure information was from urine monitoring, while that from the United States plants was from personal air monitoring, Applied Epidemiology took steps to correlate the two different types of monitoring data, applying a conversion factor published by the German government that would allow the United States air monitoring results to be expressed in concentrations of chromium in urine. Tr. at 677-678 (Mundt); CX 1 at 65. While the conversion was a rough way of correlating the two data sets, Dr. Mundt testified that he thought it would be the best solution to allow for the large cohort of workers among the four plants to be analyzed together. Tr. at 678 (Mundt).

After getting the data sets on a uniform basis through this conversion, Applied Epidemiology then created a job exposure matrix which assigned a cumulative exposure to each job category in each different plant by year. Tr. at 679-685 (Mundt); CX 1 at 59-64. Applied Epidemiology did this by matching actual exposure data to the corresponding employee's job category at the time the data was obtained, and then averaging multiple exposures per job category per year, to come up with one exposure measure per job category, per year, per plant. Id.

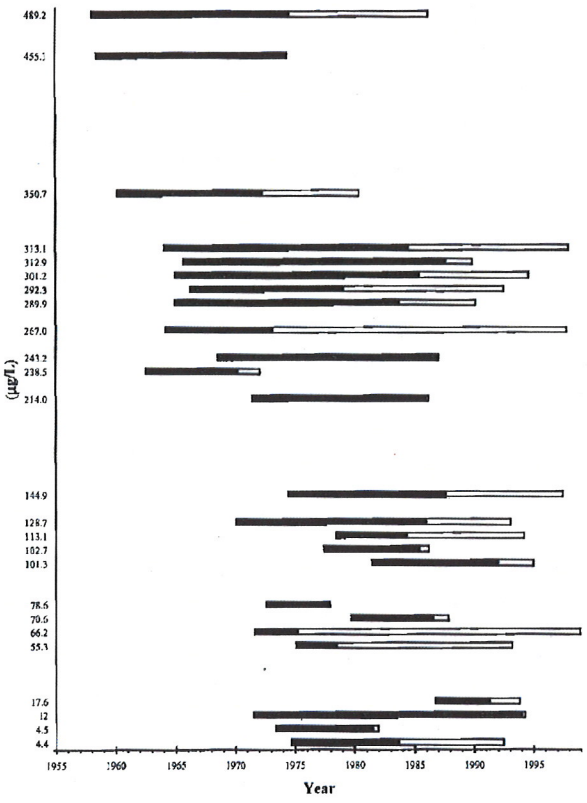
Individual cumulative exposures for each cohort member were then estimated by identifying the job category that a worker held, and using the actual exposure estimates for the job categories in the plant in which an employee worked, adjusting for the specific time period that the employee worked in the plant in each particular job (as different jobs had different exposure levels). This produced a total cumulative exposure estimate for each worker, over their full period of employment in the plant at which they were employed. Id.; Tr. at 683-684 (Mundt).

Once every worker within the cohort had an estimated cumulative exposure calculated, Applied Epidemiology then tried to determine whether each cohort member was still alive and, if not, the date and cause of death. Tr. at 685-688 (Mundt). As Dr. Mundt explained at the hearing, and as is outlined in the Final Four Plant Report, there were some difficulties in obtaining this information, but, for the most part, Applied Epidemiology was able to determine the health status for much of the cohort. Tr. at 685-688; CX 1 at 67-68.

At this point, Applied Epidemiology had a calculated cumulative exposure for each member of the cohort and a health status for most of the members of the cohort. Tr. at 689 (Mundt). Despite the EPA's witnesses assertions to the contrary, Applied Epidemiology did not determine an average exposure for any cohort member. Tr. at 688 (Mundt). Rather, Applied Epidemiology conducted its analysis using only cumulative exposures. Id.

The Report does not provide information regarding the exposure history of the specific cohort members. Thus, whether an employee's cumulative exposure was based on a short-term exposure to high concentrations or whether it was based on a long-term exposure to low concentrations, or whether it was based on a combination of the two is not provided anywhere in the Final Four Plant Report. In fact, the only place in the Final Four Plant Report where any such information is even referenced for an individual cohort member is in Figure 24, which provides, in a bar chart format, the year of hire, separation and death for the 25 lung cancer deaths observed in the cohort. CX 1 at 147 (reproduced below).

Figure 24: Year of hire, separation and death for 25 lung cancer cases



While limited only to the 25 members of the cohort who succumbed to death, this figure clearly demonstrates that the term of employment (the black portions of the bar) is not uniformly "long-term," as EPA has incorrectly stated, but rather varies greatly, as would be expected.

After calculating an estimated cumulative exposure to hexavalent chromium for each cohort member, Applied Epidemiology then gathered information on the propensity of the general population to develop certain diseases and compared that information with the health status determined for the worker cohorts. Tr. at 692-696 (Mundt); CX 1 at 70-71. The general population to which cohorts were compared were the areas where the plants were located, the common practice in epidemiology. Id. Looking at the cohort overall, Applied Epidemiology determined that there was no statistically significant

increase in disease within the cohort when compared to the general population, except with regard to disease of the respiratory system, especially with regard to disease of the trachea, bronchus and lung, i.e., lung cancer. Tr. at 697 (Mundt); CX 1 at 78, 115.[5]

In order to better understand this excess of lung cancer identified within the overall cohort, Applied Epidemiology broke the cohort into four quartiles based on cumulative exposure. CX 1 at 80; Tr. at 697 (Mundt). Applied Epidemiology conducted the further analysis to determine whether cumulative exposure was a predictor of an increased risk of lung cancer. Tr. at 697 (Mundt). The results of this analysis indicated that there was a statistically significant excess of lung cancer deaths above the expected number of lung cancer deaths, but only in the highest cumulative exposure group. Tr. at 698 (Mundt); CX 1 at 80. The three other quartiles, with lower cumulative exposures, did not evidence any statistically significant increase in lung cancer cases. CX 1 at 80, 118, Tr. at 736-741 (Mundt).

Applied Epidemiology conducted additional analyses of the data, in an effort to identify any other factors that may have contributed to this finding (such as smoking, or age), but determined that there was no such confounding influence. Tr. at 698-702 (Mundt). Thus, Applied Epidemiology concluded that the data indicated that high cumulative exposure to hexavalent chromium leads to an increased risk of lung cancer. CX 1 at 89-90. As Dr. Mundt testified, Applied Epidemiology was not able to determine what actually caused any of the 25 lung cancer deaths that they found, be it exposure to hexavalent chromium, or some other influence such as exposure to other air

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[5] Several months after delivery of the Final Four Plant Report to the Chromium Committee, Applied Epidemiology discovered a software error which resulted in a mis-calculation of the referent rates of lung cancer. When the error was corrected, Applied Epidemiology found that, contrary to what was reported in the Final Four Plant Report, there was no statistically significant increase in lung cancer at all in the cohort. Tr. at 892-893 (Mundt).

contaminants. Tr. at 844 (Mundt). However, the data, when compared to what would be expected in the general population, points to the conclusion that excessive cumulative exposure to hexavalent chromium leads to an increased lung cancer risk. Tr. at 698 (Mundt); CX 1 at 80.

Importantly given EPA's theory in this enforcement action, Applied Epidemiology did not characterize in its Report whether cumulative exposure for each member of the cohort who developed lung cancer was from long-term exposure, short-term exposure, or some mix, nor did it address, in terms of high or low intensity, the concentrations of hexavalent chromium to which the workers were exposed. In fact, Dr. Mundt testified that it would not have been valid to analyze the risk of lung cancer associated with average air concentrations of hexavalent chromium using the Final Four Plant Report cohort. Tr. at 905 (Mundt). Rather, he analyzed the cohort and those members who developed lung cancer, solely based on cumulative exposure, which does not then further attempt to correlate the results based on either the intensity or duration of the exposure. Tr. at 688, 906 (Mundt). Dr. Mundt also testified, in reference to Table 13 in the Final Four Plant Report that "[y]ou've got the full spectrum of relatively short-term to very long-term workers." Tr. at 724.

In taking this approach of correlating health outcomes to total cumulative exposure, Dr. Mundt adopted what the government's own experts acknowledge to have been the correct approach for such a study. As Dr. Clapp testified, cumulative exposure is the best measurement for this kind of study, Tr. at 431, and Dr. Speizer testified that for an occupational epidemiological study cumulative exposure is the better measure. Tr. at 524. See also, Tr. at 495, 1085 (Speizer commending Dr. Mundt's exemplary work in

conducting constructing job exposure matrices that allow development of total cumulative exposure estimate for each worker). Nor is this some post-hoc rationalization identified after this enforcement action began. As the Agency's brief itself highlights, Dr. Checkoway, a peer reviewer, commented that the value of Dr. Mundt's study would lie in "the ability to investigate dose-response relations for lung cancer." CX 3 at 51, quoted in Complainant's Initial Post-Hearing Brief, at fn. 12. And in this context, dose means cumulative exposure. Tr. at 479 (Clapp).

Thus, as discussed above, the Final Four Plant Report, which detailed the results of the study and analysis conducted by Applied Epidemiology, concluded that workers in the cohort who had been subjected to high levels of cumulative exposure to hexavalent chromium showed an increased incidence of lung cancer when compared to the general population where the plants were located. Persons in the three other exposure groups did not show a statistically significant increased incidence of cancer when compared to the general population. The Final Four Plant Report concludes that exposure to high levels of hexavalent chromium leads to an increased risk of lung cancer. This conclusion, identifying an elevated risk of lung cancer in the highest cumulative exposure group, is the only information in the Final Four Plant Report identifying a substantial risk associated with hexavalent chromium. Id.

2. The Substantial Risk Information Contained in the Final Four Plant Report Was Well Known to EPA.

As detailed above, the only information in the Final Four Plant Report that could be considered substantial risk information was the finding that the highest cumulative exposure quartile showed an elevated incidence of lung cancer, thereby leading to the conclusion that high cumulative exposure to hexavalent chromium leads to an increased

risk of lung cancer. This substantial risk information, however, was already well known to EPA because the Gibb Study, published two years prior to the preparation of the Final Four Plant Report, not only found that cumulative exposure comparable to the cumulative exposure in the highest quartile of the Final Four Plant Report caused an increased risk of lung cancer, but also that lower cumulative doses of hexavalent chromium correlated with an increased risk of lung cancer.

Elementis called Dr. Herman Gibb, the principal author of the Gibb Study, to testify at the hearing in this matter. Dr. Gibb was employed by EPA for almost thirty years. RX 6 at 1. At EPA, Dr. Gibb held the positions of Associate Director for Health and Assistant Center Director at the National Center for Environmental Assessment of EPA. RX 6 at 3. As the Associate Director for Health, Dr. Gibb was responsible for the Integrated Risk Information System (IRIS), EPA's on-line system of health risk assessments. Id. He was also the Project Officer for EPA's cooperative agreements with the World Health Organization. Id. In addition, Dr. Gibb directed EPA's assessment of inhalation exposures and potential health risks to the general population that resulted from the collapse of the World Trade Center Towers. Id. He is an author of EPA's *Guidelines for Carcinogen Risk Assessment* and *EPA's Risk Assessment Principles and Practices*. RX 6 at 1 Dr. Gibb was the recipient of the EPA's Scientific and Technological Achievement Award for his study of lung cancer mortality and clinical irritation among chromate production workers and the recipient of the EPA's Gold Medal for Exceptional Service for his work on the drinking water standard for arsenic. Id. His study of chromate production workers utilized one of the most extensive industrial hygiene databases ever assembled in its analysis of the lung cancer risk from hexavalent

chromium. Id. The study formed the basis of OSHA's Permissible Exposure Limit (PEL) on Hexavalent Chromium. Id.

At the hearing, Dr. Gibb testified that when he was the Assistant Center Director for the National Center for Environmental Assessment at EPA, he conducted an epidemiological study of chromate workers who had worked at a plant in Baltimore, Maryland. Tr. at 1029-1040 (Gibb). Similar to the Final Four Plant Report, Dr. Gibb testified that he calculated an estimated cumulative exposure for the workers in the Baltimore plant using a job exposure matrix. Tr. at 1032; CX 62 at 4. Dr. Gibb also testified that, as with the Final Four Plant Report, he did not correlate the average air concentration for cohort members with lung cancer risk. Tr. at 1038. Indeed, Dr. Gibb testified that given the ability to build exposures based on specific job matrices, and to then segregate workers by exposure quartiles, it would have been a misuse of the data to take a simplistic overall average of air concentrations to compute any kind of risk assessment. Tr. at 1038-1039. Also similar to the Final Four Plant Report, Dr. Gibb determined the health status of each member of the cohort and compared the health status of the cohort members with a reference population, in this case, the state of Maryland. CX 62 at 4.

Dr. Gibb's study found that certain levels of cumulative hexavalent chromium exposure was associated with an increased risk of lung cancer. Tr. at 1037; CX 62 at 1. To further analyze the risk of lung cancer from the cumulative exposure to hexavalent chromium, Dr. Gibb divided his cohort into quartiles based on cumulative exposure, just as was done in the Final Four Plant Report. CX 62 at 7

Dr. Gibb found that workers in his lowest two quartiles by cumulative exposure did not show a statistically significant increased risk of lung cancer. CX 62 at 8, Table VI. However, for the highest two quartiles, Dr. Gibb identified a statistically increased risk of lung cancer. Id.

Both the Final Four Plant Report and the EPA study conducted by Dr. Gibb looked at cumulative exposure as the metric of dose. As noted above, EPA's witnesses, Dr. Clapp and Dr. Speizer, agreed that cumulative exposure is the correct measure of dose for occupational epidemiology studies investigating lung cancer. Tr. at 431 (Clapp); Tr. at 524 (Speizer). In turn, both studies' use of cumulative exposure as the dose metric allows their results to be compared. EPA provides this comparison in its Exhibit CX 99.[6] As Dr. Gibb, Dr. Mundt and the Agency's own witnesses testified at the hearing, CX 99 clearly demonstrates that the Gibb Study found an increased risk of lung cancer at much lower cumulative exposure levels than the Final Four Plant Report. Tr. at 909 (Mundt); Tr. at 1045-1046 (Gibb); Tr. at 241 (Cooper); Tr. at 436-440 (Clapp); Tr. at 1097-1098 (Speizer). The increased risk found by the Gibb Study was at a cumulative exposure more than 20 times lower than that found by the Final Four Plant Report. Tr. at 1046 (Gibb). Importantly, the Final Four Plant study did not find a risk at any doses lower than where risk was found in the Gibb Study, only at higher doses. See CX 99.

Using the cigarette smoking analogy presented by EPA's witness, Dr. Cooper, if the Gibb Study and the Final Four Plant study were cigarette smoker studies rather than occupational hexavalent chromium studies, the Gibb Study would have found that, to

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[6] To do so requires that the units of cumulative exposure used in each study be matched. [cite to Barnhart] Because the Final Four Plant Report provided the cumulative exposure in urine concentration-based units (ug/l), that Report's results had to be converted to air-based measurements [cite to Barnhart]. This is done by applying the conversion factor of .77 utilized by Dr. Mundt to originally convert the air measurements from the U.S. plants to urine concentrations.

cause lung cancer, it takes significantly fewer total lifetime cigarettes smoked than the amount found by the Final Four Plant Report. Because the Final Four Plant Report did not find a substantial risk at a dose lower than what had been previously found in the Gibb Study, the Final Four Plant Report did not identify a significant new risk associated with hexavalent chromium, rather it just found risk where it was already known to exist based on the previously-conducted Gibb Study. As EPA was well aware of the Gibb Study, having funded it, it having been conducted by a senior EPA researcher and manager, and it having been published two years prior to Elementis' receipt of the Final Four Plant Report, it necessarily follows that EPA was already well aware of the substantial risk information identified in the Final Four Plant Report.

3. Elementis Knew That EPA Was Already Adequately Informed of the Substantial Risk Information Identified by the Final Four Plant Report.

Dr. Barnhart testified at the hearing that he received a draft of the Final Four Plant Report in early 2002. Tr. at 969 (Barnhart). At that time, he reviewed the draft and recognized that the study conducted by Applied Epidemiology had found no adverse effect other than a slightly elevated lung cancer risk in the overall group. Tr. at 971 (Barnhart). He then looked at the quartiles of cumulative exposure and saw that only the highest of the groups showed a statistically significant Standard Mortality Ratio ("SMR") above one, i.e. the slight increase in the overall group was wholly a function of the increased risk in the highest quartile, not the product of risk distributed across the full worker cohort. Tr. at 971-972 (Barnhart).

The estimated cumulative exposures for hexavalent chromium in the draft Final Four Plant Report were reported as hexavalent chromium in urine. CX 1 at 118. Dr. Barnhart, however, was interested in how the cumulative exposures correlated to

chromium in air, which he understood was the parameter most of interest to OSHA and EPA. Tr. at 972 (Barnhart). Also, Dr. Barnhart testified that he wanted to determine how these results "fit in with what had been known." Id. He realized that the Gibb Study had been recently published and it had been reported using cumulative exposures in air. Tr. at 973 (Barnhart). Comparing the finding of substantial risk in the Final Four Plant Report with the findings in the Gibb Study would provide a good reference about whether the substantial risk finding in the Final Four Plant Report represented new insight. Tr. at 984 (Barnhart).

In order to have a single value for the highest cumulative exposure quartile in the Final Four Plant Report, Dr. Barnhart chose a value somewhat above the lower bound cumulative value in the fourth quartile, which was 200 ug/l years, to represent a mean value for the quartile. Tr. at 980 (Barnhart). The value Dr. Barnhart chose was 250 ug/l years, which was conservatively low. Id. He then performed certain conversion calculations to insure that the two studies were on a common measurement basis for cumulative hexavalent chromium air exposure. Tr. at 980-982 (Barnhart).

After the conversions, Dr. Barnhart compared the mean cumulative exposure for the highest quartile in the Gibb Study, which was 225 ug cr^{+6}/m^3 years, and which had a statistically significant SMR of 2.24 to the 325 ug cr^{+6}/m^3 years he had calculated from the draft Final Four Plant Report. Tr. at 982-983 (Barnhart). Based on this comparison, he concluded, within the first few days of getting the draft, that as to the level at which an increased cancer risk emerged, "this data [i.e. the Four Plant Report data] falls in same range more or less as the Gibb data." Tr. at 983 (Barnhart).

Dr. Barnhart further testified that he knew the Gibb Study had been published in 2000, two years before he had received the draft Final Four Plant Report. Tr. at 984 (Barnhart). He also testified that he had attended a number of presentations by Dr. Gibb or Dr. Gibbs' co-author, Dr. Lee, about the Gibb Study and thus was already familiar with the information in it. Id. Dr. Barnhart also knew that Dr. Gibb worked for EPA and thus knew that EPA was aware of the Gibb Study. Tr. at 985-986 (Barnhart). Because he had already determined that the Gibb Study found elevated risk at a cumulative exposure less than the level at which the Final Four Plant Report identified the risk, Dr. Barnhart correctly concluded that EPA was already adequately informed of this risk.

At that time, Dr. Barnhart's understanding of TSCA Section 8(e) was that it required a company to provide information to EPA if "something new came out that was significant, showing an adverse effect that was especially unexpected or much greater than expected." Tr. at 991 (Barnhart). And, with this understanding, and after this comparison of the results reported in the draft Final Four Plant Report to the information in the Gibb Study, he determined that there was no requirement to report the information in the draft Final Four Plant Report. Tr. at 991 (Barnhart).

Finally, when Dr. Barnhart received the Final Four Plant Report in September 2002, he reviewed the report and did not see anything different in the final version when compared to the draft. Tr. at 992-993. (Barnhart) Thus, his earlier conclusions reached after reviewing the draft, had no reason to change.

The testimony by Dr. Barnhart clearly demonstrates that Elementis knew that EPA was adequately informed of the only substantial risk information in the Final Four

Plant Report, namely that high cumulative exposure to hexavalent chromium increased the risk of lung cancer.

B. EPA's Guidance Supports Elementis' Decision That TSCA Section 8(e) Did Not Require It To Provide The Final Four Plant Report To EPA.

At the time that EPA alleges Elementis was required to provide the Final Four Plant Report to the Agency in October 2002, and indeed to this day, there were no regulations promulgated regarding Section 8(e)'s reporting requirement. Instead, there are only a 1978 EPA "policy" document and a 1991 EPA "Reporting Guide ." Both of these documents, although not promulgated regulations, were intended to set forth "the Administrator's interpretation of and policy towards section 8(e)..." and "assist the potential respondents who manufacture, import, process or distribute chemical substances in complying with Section 8(e)..." (CX 17 at 2, CX 21 at 2).

The 1978 document, identified by EPA in the document as a "policy statement" (CX 17 at 1), provides that information on "[a]ny instance of cancer" is considered by EPA to be "substantial-risk information." Such substantial-risk information must be reported to EPA if it comes from a "[d]esigned, controlled study" such as an epidemiological study, unless a) "[i]nformation respecting these effects can be ... inferred from designed studies as discussed in Part VI [of the policy statement]," or b) it is exempt from reporting pursuant to Part VII of the policy statement.

Part VII of the policy statement provides that:

> Information need not be reported if it:
>
> * * *
>
> (d) Is corroborative of well-established adverse effects already documented in the scientific literature and referenced as described in (c) above ...

Elementis concedes that the Final Four Plant Report was an epidemiological study. Elementis further concedes that the Final Four Plant Report identified an "instance of cancer" outside of the ordinary because it identified a statistically significant increased risk of lung cancer in the highest cumulatively exposed group of workers. However, because the finding simply corroborated a well-established adverse affect associated with hexavalent chromium, namely that high cumulative exposure to hexavalent chromium leads to an increased risk of lung cancer, under the 1978 policy statement from EPA, the Final Four Plant Report did not have to be reported under TSCA Section 8(e).

As detailed above, and as further established and explained at the hearing, the Final Four Plant Report indicated an increased risk of lung cancer in the highest cumulative exposure quartile, but did not find an increased risk of lung cancer in any of the lower three quartiles. CX 1 at 118; Tr. at 737 (Mundt). When compared to the Gibb Study, which also analyzed risk of lung cancer to workers based on cumulative exposure to hexavalent chromium, the Gibb Study found an increased risk of lung cancer at much lower cumulative exposures. CX 99; Tr. at 1046 (Gibb). Thus, Elementis concluded that the results of the Final Four Plant Report simply corroborated what Dr. Gibb and EPA had already found. Tr. at 982-983 (Barnhart). EPA presented no evidence at the hearing to refute Elementis' determination that the Gibb Study showed a risk of lung cancer at cumulative exposures that were lower than the cumulative exposure where the Final Four Plant Report first showed a risk. In fact, EPA produced CX 99, which clearly and unequivocally demonstrates this fact. Thus, the only finding of substantial risk associated with hexavalent chromium in the Final Four Plant Report had already been well-established through the Gibb Study. Again, using Dr. Cooper's analogy to cigarette

smoking, if a study found an elevated risk from smoking a lifetime cumulative amount of cigarettes, it established nothing new when a later study is done, that shows that smoking more than that amount in a lifetime will also increase risk compared to the general population. In turn, under a plain reading of the 1978 guidance and given the results reported in the Gibb Study and the Final Four Plant Report, Elementis was not required to report this corroborative information.

The 1991 guidance document provides further clarity on what constitutes corroborative information that does not have to be reported under TSCA Section 8(e). Specifically, that guidance notes that

> [t]here are several kinds of information about which the Agency considers itself to be adequately informed already for the purposes of Section 8(e) of TSCA. For example, information that otherwise meets the criteria for Section 8(e) reporting need not be submitted if the information meets one or more of the following criteria:
>
> * * *
>
> (5) is corroborative (in terms of, for example, route of exposure, dose, species, time to onset, severity, species [sic], strain, etc.) of a well-established adverse effect.

When questioned by the Presiding Officer, EPA's witness, Dr. Clapp, admitted that the Gibb Study and the Final Four Plant Report were the same in terms of dose (cumulative exposure), species (human) and severity (lung cancer). Tr. at 480-482. Dr. Clapp testified that strain was not applicable because that would only apply to animal studies. Id. However, Dr. Clapp testified that the two studies were different in terms of time to onset, which he explained as follows:

> THE WITNESS: Well, that is referred to as the wait and see, I think, between the initial exposure or the initial potential exposure and then dying from lung cancer. And that was different in these two studies.

Tr. at 481 (Clapp). However, under Dr. Clapp's definition of time to onset, even members of the same cohort would have different time to onset, because it would be only coincidence that two people had the exact same time from initial exposure to death. The fact is that neither the Gibb Study nor the Final Four Plant Report analyzed whether their respective cohorts provided any substantial risk information about time to onset, and Dr. Clapp's bare assertion that the reports differ in this respect, with no citation to any aspect of either report, cannot establish the fact. In short, it is impossible to credibly claim the studies differed with regard to time to onset because neither study analyzed it.

A further clarification provided by EPA in its reporting guidance is particularly informative:

> It is important to note, however, that information that newly identifies a serious toxic effect at a lower dose level for example, or confirms a serious effect that was previously only suspected, is not considered by EPA to be corroborative and should be reported under Section 8(e) of TSCA.

Of course, the converse of noting that identifying a toxic effect at a "lower dose level" is new is that identifying a toxic effect at a higher dose level is not new. And as explained at length above, the testimony at the hearing in this matter, as well as EPA's own Exhibit (CX 99), demonstrate without question that the Final Four Plant Report identified a serious toxic effect associated with hexavalent chromium, but only at a higher dose than what had already been found in the Gibb Study. Furthermore, while the Final Four Plant Report also confirmed the bare fact that hexavalent chromium exposure is associated with lung cancer, this effect has been reported by EPA since at least their 1984 Health Assessment Document for Chromium. RX 25. Therefore, turning to EPA's own

guidance further establishes that Elementis correctly concluded that the Final Four Plant Report did not have to be provided under TSCA Section 8(e).

C. EPA's Effort To Treat The Final Four Plant Report As New Because Of Alleged Differences In Worker Cohorts In The Gibb Study Is Not Valid

In an effort to remake or ignore the actual findings in the Final Four Plant Report, EPA now stakes its enforcement action on the claim that risk information in the Final Four Plant Report is "new" because the workers studied in that report are alleged to have had different exposure profiles than those studied in Gibb – the so-called high intensity/short term v. low intensity/long-term dichotomy. This argument fails as a matter of law, regulatory policy and fact.

First, whatever might have been the manner in which workers were exposed (low intensity/long term v. high intensity/short term), the witnesses – including EPA's own experts – routinely acknowledged that the critical and appropriate starting point for performing an epidemiological risk analysis such as that in the Gibb and the Final Four Plant Study is to work from cumulative total exposure. Thus, the Agency, in focusing on the alleged differences in exposure intensity/work duration, at best points out an irrelevant distinction between the two studies. Given the fact that it is cumulative total exposure that is relevant in assessing risk, and identical cumulative exposures can result from multiple exposure scenarios, the Agency's resort to this purported distinction even if true, is true only as to a fact that is irrelevant.

Second, neither the Final Four Plant Report nor the Gibb Study reported any increased risk information in which the risk was correlated to the high intensity/short duration or low intensity/long duration on which EPA now plants its flag. This lack of findings is unsurprising as neither the Final Four Plant Report nor the Gibb Study, in fact,

assessed duration or intensity of exposures of their respective cohorts. Thus, EPA's position relies not on what the Final Four Plant Report actually reports or what the Gibb Study reports but on what EPA believes it might be read to suggest based on further manipulation, evaluation and interpolation. But such an approach depends on both scientific and regulatory overreach to now characterize the two studies as distinguishable on this basis. In turn, it must be rejected.

Third, there is ample evidence that the cohort in the Final Four Plant Report included a wide range of exposures from short-term exposures to very long-term exposures, as well both high-intensity exposures and low-intensity exposures. Similarly, the Gibb Study cohort also included a wide range of exposures from short-term exposures to very long-term exposures, as well as both high-intensity exposures and low-intensity exposures. Thus, because of the high variability of duration and exposure intensity in both studies, use of averages of duration and air concentration mischaracterize the cohorts. Finally, in determining average exposure intensities, EPA utilized data that was not representative of the cohort.

For all of these reasons, as more fully addressed below, the distinctions that EPA draws between the Final Four Plant Report and the Gibb Study are both legally irrelevant and factually baseless and cannot therefore form a basis on which to conclude that Elementis violated TSCA Section 8(e).

1. EPA's Witnesses Acknowledge that the Appropriate Manner in Which to Assess Risk in Studies Such as the Gibb Study and the Final Four Plant Report is by Focus on Total Cumulative Exposure.

As discussed above, both the Gibb Study and the Final Four Plant Report estimated each cohort member's cumulative exposure to hexavalent chromium (Tr. at 682

(Mundt); CX 1 at 66; CX 99; Tr. at 1046 (Gibb)) and concluded that increased risk emerged only in connection with certain cumulative worker exposures. Moreover, it is common ground between all experts – Mundt, Gibb, Clapp and Speizer – that cumulative exposure is the accepted and best way to assess risk associated with occupational exposure to chromium. See, e.g., Tr. at 431 (Clapp); Tr. at 524 (Speizer). Indeed, the Agency's initial brief goes on at great length to explain the different ways in which the same total cumulative exposure may come about. See Complainant's Initial Brief, at 32.

Yet, despite acknowledging that it is total cumulative exposure that matters in assessing risk, the Agency now wants to distinguish the Final Four Plant Report from the Gibb Study on the basis that workers in each may have come to their total exposures through different scenarios. Even if true (a point further addressed below), for purposes of TSCA 8(e) that is an irrelevancy. It is likely equally true that the populations had different hair colors, different average heights, different average ages, and many other differences. But none of the experts suggested that these other factors related to risk – rather they all agreed that cumulative exposure is the way to assess risk. Thus, even if true, differences in worker exposure scenarios cannot be a basis on which to conclude that the Final Four Plant Study presented new risk information. Had the Final Four Plant Report found some different heightened risk, previously unknown at a certain total cumulative exposure level, this would be a different case. But that is not what the Final Four Plant Report found – instead it confirmed only what was already known through Gibb and other studies previously conducted.

Finally, the implications of EPA's approach bear noting as to whether EPA's position can be consistent with the statute or EPA's regulations. For occupational

epidemiological studies such as the Gibb and Final Four Plant studies there will always be differences in the cohorts – two cohorts will always have varying employment tenures, and different exposure intensities. That is precisely why such studies coalesce around total cumulative exposure as a metric for measuring risk. But in EPA's view, given such differences, it will be impossible for any occupational epidemiological exposure study not to demonstrate new risk, as every time that risk will have, by assumption, emerged in a different context that the Agency regards as significant under TSCA 8(e). But nothing in TSCA 8(e) suggests that such studies were meant to be outside the bounds of TSCAs' exception for corroborative information. Yet that is precisely what EPA will accomplish if it prevails here. Equally troubling, it will have done so relying on such vague concepts as "long term/low intensity" and "short term/high intensity" – terms having no discernible scientific meaning against which no rational regulatory decision-making can be based, either by the regulators or the regulated. Moreover, in achieving this result, EPA will have effectively, and sub silencio, repudiated its own 1991 Guidance, which clearly contemplates that epidemiological studies showing risk as similar dose need not be reported.

2. EPA's Approach Requires a Rewriting of the Final Four Plant and Gibb Studies, Taking Their Implications Well-Beyond What the Reports Themselves Establish and Contrary to the Statute.

The Agency's approach suffers a second legally fundamental defect – to establish its position it must go well-beyond the risk information actually presented in either report. As discussed at length above, the only risk relationship either study itself reported was one rooted in total cumulative exposure. Neither study successfully correlated a risk to either of the dimensions EPA now suggests is relevant independently – length of exposure or exposure intensity. As explained above, and at the hearing in this matter, the

Final Four Plant Report estimated each cohort member's cumulative exposure to hexavalent chromium. Tr. at 682 (Mundt); CX 1 at 66. This was done through the use of a job exposure matrix developed by Applied Epidemiology, utilizing exposure data at each facility. Tr. at 680-682 (Mundt); CX 1 at 66-67.

Nowhere in the Final Four Plant Report does Applied Epidemiology report on or analyze the length of an individual's exposure to hexavalent chromium or the intensity (i.e., concentration) of that exposure. As explained by Dr. Mundt at the hearing and in the Final Four Plant Report, only a worker's cumulative exposure was determined by applying the job exposure matrix to that person's employment record. Tr. at 682 (Mundt); CX 1 at 66-67. By way of example, a hypothetical worker who had worked in the Leverkusen plant from 1958 to 1988, spent the first ten years as a Lab Technician (CX 1, Figure 13), and then spent the remaining 20 years in the Sulfate Separation & Drying operation (CX 1, Figure 12). Based on the figures of average exposures in the areas revealed of Figures 12 and 13 in the Final Four Plant Report, this worker would have experienced many different intensities of exposure over those thirty years. Instead of averaging all of those intensities (air concentrations), the Final Four Plant Report expressed that worker's exposure as one cumulative exposure, an accumulation of the different exposures over the course of that employee's work history.

In the study conducted at the Four Plants by Applied Epidemiology, each member of the cohort was assigned a single cumulative exposure value, not an average exposure and duration. Similarly, the Gibb Study determined one single cumulative exposure value for each cohort member. Neither study, however, calculated an average exposure

for any of its cohort members, and EPA has not cited to any such determination in either report.

Instead, to validate its claim that the cohorts in Gibb Study and the Final Four Plant Report differed materially, EPA relies on a series of calculations, estimations and manipulations nowhere contained in the studies themselves. See, e.g. Complainant's Initial Brief, at 31-32, explaining the multiple steps it takes to extrapolate the low level/high level distinction. This alone is a further sufficient reason to reject EPA's position. TSCA 8(e) only requires a company to report "information" that it has received and not previously known. But EPA now, in distinguishing the Gibb Study from the Final Four Plant Report, instead relies on after-the-fact calculations and manipulations that the Agency itself has conducted and finds significant. In doing so, it depends on "information" that Elementis never possessed. To the contrary, the only risk information as to which Elementis was aware was the risk associated with the high cumulative exposure quartile.

And, again, the implications of EPA's position bear noting. In seeking to extend the reporting obligation on the theory advanced here, EPA essentially seeks to write the 8(e) reporting exception out of the statute. No company could ever have confidence that a study it received, indeed even one concluding there was no evidence of risk, would not be susceptible to a later Agency reinterpretation that would render the study new reportable information. Such an outcome might be distinctively to the Agency's liking ("give it all to us, we'll decide") but that is, most assuredly, not the scheme that Congress devised. In turn, EPA cannot prevail here.

3. The Cohorts in Both the Final Four Plant Report and the Gibb Study Contained Workers Who Ranged From Short-Term to Long-Term and EPA's Use of Cohort-Wide Means of Exposure Duration and Average Air Concentration is Invalid to Characterize the Cohort.

Finally, EPA contends that exposures in the Final Four Plant Report were "long-term" exposures. However, as reflected in Table 9 of the Final Four Plant Report (reproduced below), the duration of exposure for the workers in the cohort in each of the four plants varied greatly:

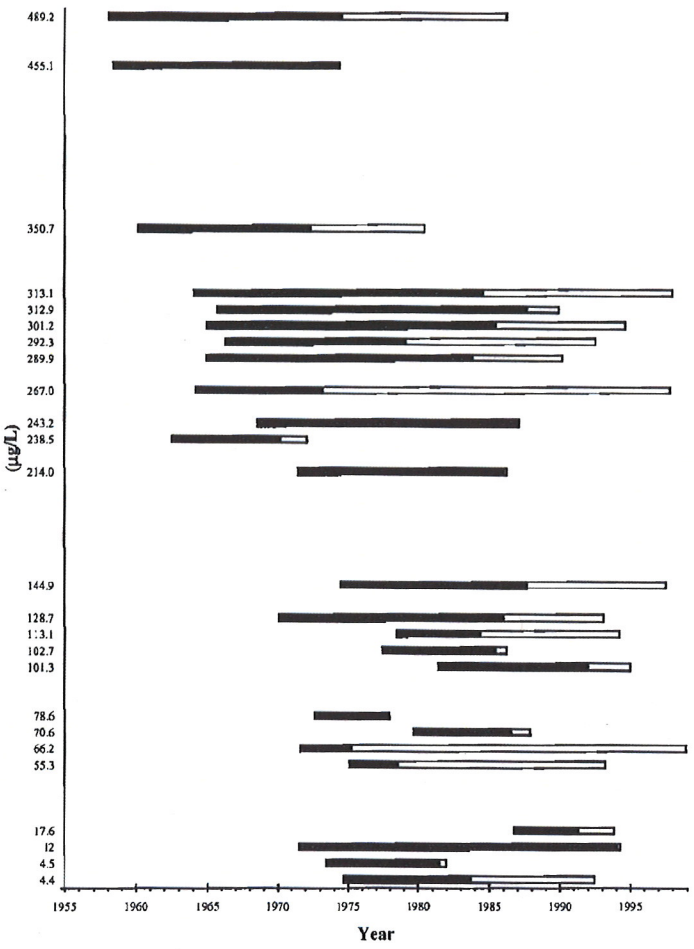
Leverkusen range	1.0 years to 40.7 years
Uerdingen range	1.0 years to 29.4 years
Castle Hayne range	1.0 years to 27.9 years
Corpus Christi range	1.0 years to 17.9 years

Table 9: Duration of exposure and time since first exposure by plant

	Leverkusen (n=593)	Uerdingen (n=308)	Castle Hayne (n=430)	Corpus Christi (n=187)
Duration of exposure				
Mean	9.2	11.0	12.4	7.8
SD	6.3	6.6	9.5	5.1
Range	1.0 – 40.7	1.0 – 29.4	1.0 – 27.9	1.0 – 17.9
Time since first exposure				
Mean	16.4	19.1	20.1	10.1
SD	9.9	8.2	7.7	5.0
Range	1.0 – 40.9	2.0 – 34.9	1.4 – 28.8	1.0 – 17.9
Age at first exposure				
Mean	38.4	37.7	28.9	31.3
SD	10.6	6.2	8.3	7.4
Range	14.6 – 60.5	19.2 – 53.1	17.4 – 62.9	19.9 – 53.5

CX 1 at 113. Furthermore, in referencing the duration of exposure in the Final Four Plant Study, Dr. Mundt testified that "there's a lot of variability across plants and within plants. You've got the full spectrum of relatively short-term to very long-term workers." Tr. at 724 (Mundt). Furthermore, Figure 24 in the Final Four Plant Report (reproduced below) shows the year of hire, date of separation and date of death for the 25 cohort members who died of lung cancer.

Figure 24: Year of hire, separation and death for 25 lung cancer cases



As can be plainly seen, the duration of exposure for just these 25 cohort members (represented by the black bar) varies greatly. CX 1 at 147.

EPA's erroneous contention that the workers in the Final Four Plant Study were long-term is based solely on the average duration of exposure. However, for the Final Four Plant Report cohort, where there is significant variability in the duration of exposure across the cohort, using an average to characterize the duration misrepresents the facts and is highly misleading.

In addition, the Gibb Study, which EPA characterized as a cohort of short-term exposure duration, reported in Table II (reproduced below) that its cohort work years

ranged from .003 years to 37.7. CX 62 at 6. More importantly, its range of lung cancer cases ranged from .003 years of exposure to 32.2 years of exposure. Id.

TABLE II. Description of Entire Cohort by Cumulative Hexavalent Chromium Exposure, Cumulative Trivalent Chromium Exposure, Years of Work at the Plant, Age at Hire, Years of Follow up, and Calendar Year of Hire [N (Total Group) = 2,357, N (Lung Cancer Cases) = 122, N (Noncases) = 2,235]: Chromium Chemical Production Workers, USA

Variable / Statistic	Cumulative hexavalent chromium exposure (mg/m^3-years)	Cumulative trivalent chromium exposure (mg/m^3-years)	Work years	Years of follow up	Age at hire	Calendar year of hire (19XX)
Mean						
Total group	0.134	1.98	3.1	30.0	30.2	57.7
Lung cancer cases	0.290	3.57	5.3	27.9	33.3	53.5
Noncases	0.125	1.90	3.0	30.1	30.0	58.0
Standard deviation						
Total group	0.357	5.28	6.5	9.6	7.5	7.7
Lung cancer cases	0.620	7.39	9.1	8.5	8.8	4.1
Noncases	0.335	5.13	6.3	9.7	7.4	7.8
Median						
Total group	0.009	0.11	0.39	31.2	28.6	54
Lung cancer cases	0.016	0.22	0.84	28.9	31.6	53
Noncases	0.009	0.11	0.41	31.3	28.5	54
Min/max						
Total group	0/5.3	0/64.7	0.003/37.7	0.3/42.3	16.9/62.9	50/74
Lung cancer cases	0/4.1	0/36.4	0.003/32.2	6.4/42.2	21.2/62.6	50/73
Noncases	0/5.3	0/64.7	0.003/37.9	0.3/42.4	16.9/62.9	50/74
25th percentile						
Total group	0.001	0.014	0.088	22.6	24.3	51
Lung cancer cases	0.002	0.024	0.167	22.1	26.3	51
Noncases	0.001	0.014	0.085	22.7	24.3	51
75th percentile						
Total group	0.076	0.98	2.0	38.9	34.4	65
Lung cancer cases	0.226	2.79	4.6	35.1	39.2	54
Noncases	0.072	0.94	2.0	39.2	34.2	65

Certainly, cohort members who had been exposed for 37.7 and 32.2 years cannot possibly be coined "short-term."

EPA has also argued that exposures to hexavalent chromium in the Final Four Plant Report cohort were low-intensity. However, this is belied by the report itself which provides, in graphical form, the exposures in various work areas at the four plants in the study. A review of Figures 6 to 21 in the Final Four Plant Report (CX 1 at 129 to 144) clearly reveals that the intensity of exposures varied greatly and was very high at times in the Saturation plant in Uerdingen (Figure 6, CX 1 at 129 (reproduced below)), the ADC/KDC production in Uerdingen (Figure 7, CX 1 at 130 (reproduced below)), Shipping in Uerdingen (Figure 8, CX 1 at 131 (reproduced below)), Kiln 1 at Leverkusen (Figure 10, CX 1 at 133 (reproduced below)), the Sulfate Separation and Drying operation at Leverkusen (Figure 12, CX 1 at 135 (reproduced below)), Shipping in

Corpus Christi (Figure 14, CX 1 at 137 (reproduced below)) and the DCS Kiln in Corpus Christi (Figure 15, CX 1 at 138 (reproduced below)).

Figure 6. Saturation - Uerdingen

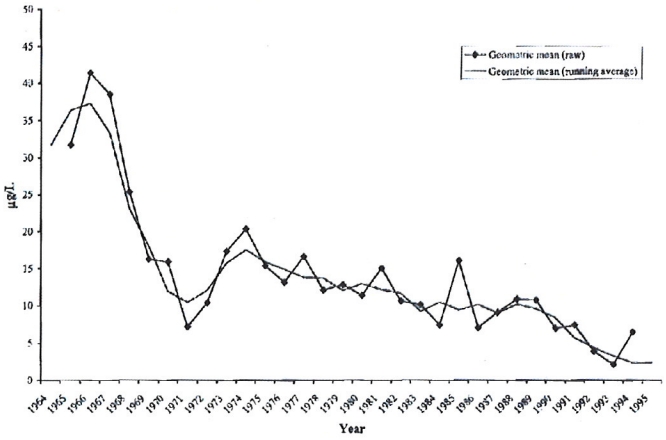


Figure 7: ADC/KDC production - Uerdingen

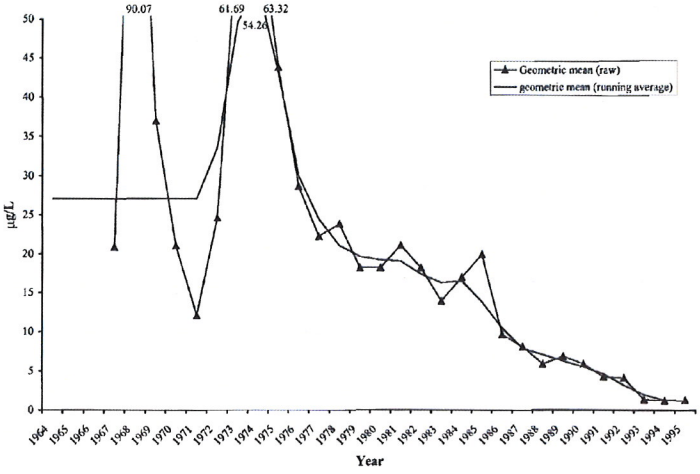


Figure 8: Shipping – Uerdingen

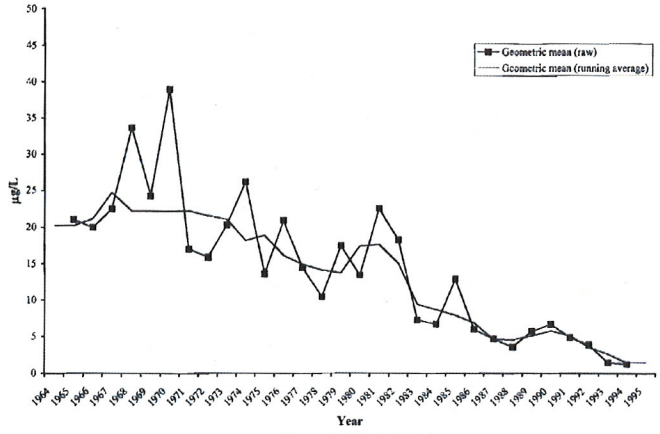


Figure 10: Kiln 1 - Leverkusen

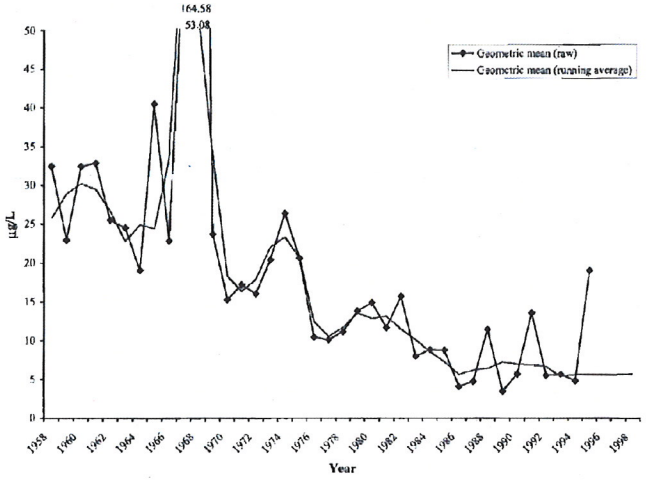


Figure 12: Sulfate Separation & Drying - Leverkusen

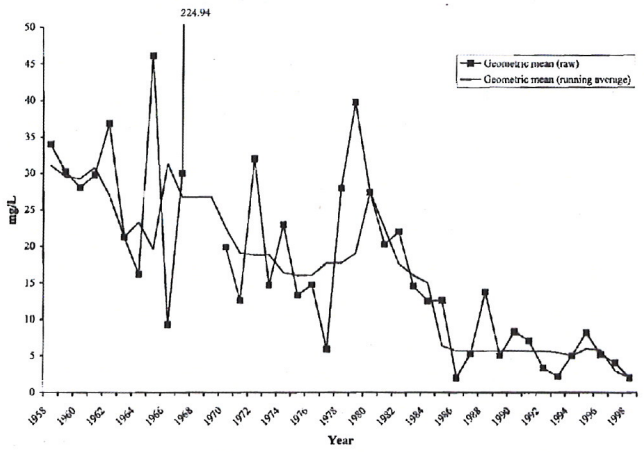


Figure 14: Shipping – Corpus Christi

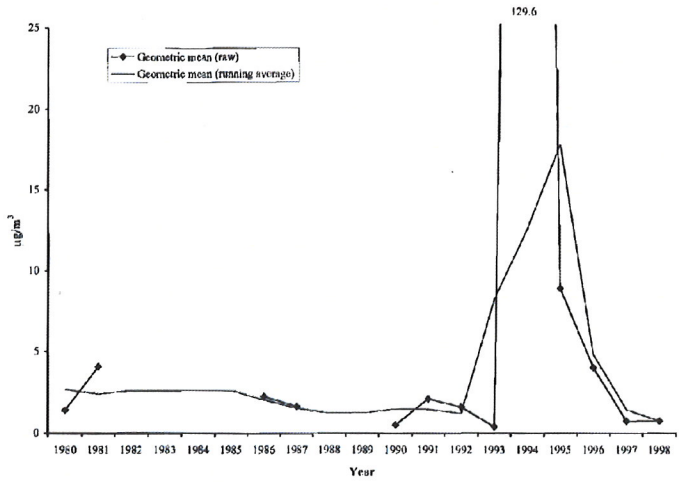
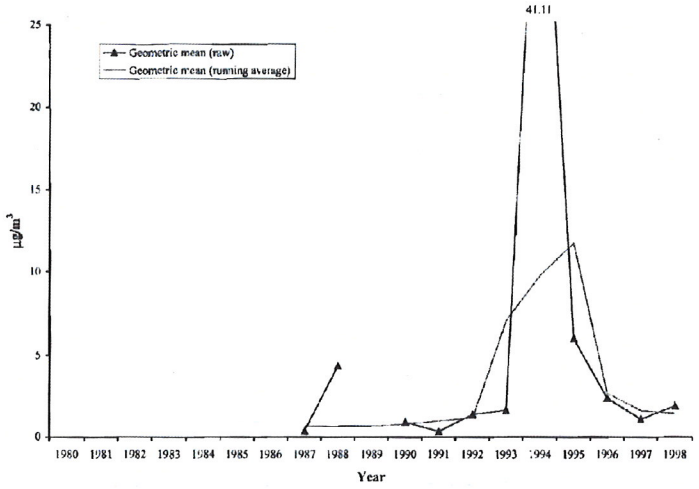


Figure 15: DCS Kiln – Corpus Christi



These figures convincingly refute EPA's contention that the exposures in the Final Four Plant Report were "low-intensity."

EPA attempts to prove that the Final Four Plant Report was limited to long-term, low-intensity exposure, while the Gibb Study looked only at high-intensity, short-term exposures by calculating the average duration of exposure in each study and the average air concentration in each study.

EPA tries to contrast them by comparing averages of the length of employment of the cohorts as well as the average concentrations in each of the facilities. However, EPA's methodology is fatally flawed because the measure of exposure utilized by both studies, cumulative exposure, does not provide any individual cohort member's duration of exposure or the various concentrations of hexavalent chromium in the air that employee may have experienced over the course of his or her employment.

Dr. Cooper tried to demonstrate the difference between the two studies by an analogy to cigarette smoking. Tr. at 145, 270-271 (Cooper). However, because neither the Final Four Plant Report nor the Gibb Study analyzed for, or reported, an individual cohort member's average concentration (pack per day) of duration of exposure (number of years smoking), there is no way to appropriately compare the two studies on these bases. Instead, what Dr. Cooper did was to say that because the Gibb Study included people who had worked at the Baltimore plant for less than a year in the study (smokers who only smoked for a few weeks) and the Final Four Plant Report did not include smokers who had smoked for less than a year, that the duration of time that all of the members of the Gibb cohort worked was lower than the duration of time that the workers in the entire Final Four Plant Report cohort worked in the plants. The obvious error of relying on the average duration is apparent because inclusion of the short-term workers in the Gibb Study greatly skewed the average duration of employment downward.

In fact, correctly applying the EPA cigarette analogy to what actually was done in both the Gibb Study as well as the Final Four Plant Report, one sees that both the intensity of the exposure (packs per day) and the duration of exposure (years of smoking)

were eliminated from the analyses because both studies only considered the cumulative exposure (total number of cigarettes smoked in a lifetime).

By way of example, because both the Gibb Study and the Final Four Plant Report only estimated cumulative exposure to hexavalent chromium, the analogy for cigarettes would be as follows: Smoker A smoked 3 packs per day for 10 years, or 30 pack years cumulatively:

3 packs/day x 10 years = **30 pack years**

Smoker B smoked 2 packs per day for 4 years during college, cut back to 1 pack per day for 12 years, at age 30 cut back to 5 cigarettes per day and then quit smoking when he was 70. Smoker B thus smoked a cumulative of 30 pack years:

2 packs/day x 4 years = 8 pack years + 1 pack/day x 12 years = 12 pack years + ¼ pack/day x 40 years = 10 pack years 8 pack years + 12 pack years + 10 pack years= **30 pack years**

As can be seen by the example of these two smokers, both the duration of smoking time and the intensity vary greatly between Smoker A and Smoker B. However, if you are only provided with the cumulative values, which are the same in this example, it is not possible to determine either the intensity or the duration of either Smoker A or Smoker B. They both smoked a cumulative total of 30 pack years. However, Smoker A did it in 10 years, whereas Smoker B took 56 years to smoke that many cigarettes. Furthermore, Smoker A was a very heavy smoker for 10 years, while the smoking intensity for Smoker B varied significantly over the 56 years. But these differences

between the two smokers' duration of exposure or intensity of exposure cannot be drawn from the cumulative figure.

Similarly, it is not possible to draw conclusions about a chromium plant worker's intensity or duration of exposure when only a cumulative estimate is calculated, as was done in both the Final Four Plant Report as well as the Gibb Study. For instance, Worker A worked from 1965 to 1972 in the Kiln 1 area at the Leverkusen plant, and then worked the next 16 years as a laboratory technician in the Leverkusen plant. Worker A's average exposures are represented in the highlighted portions of the graphs below:

Figure 10: Kiln 1 - Leverkusen

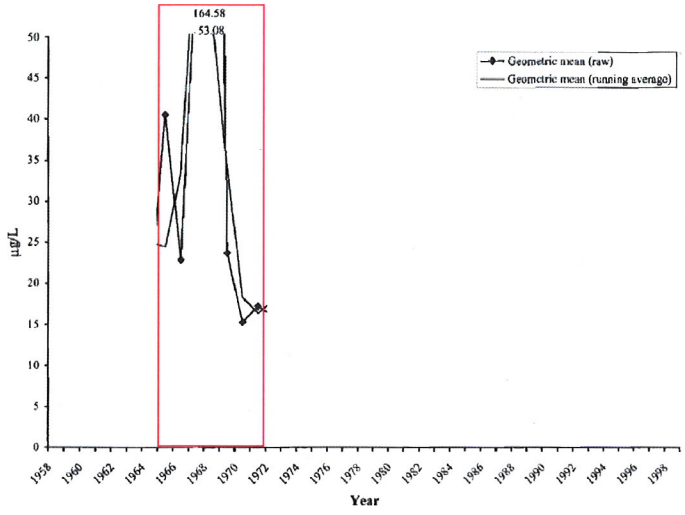
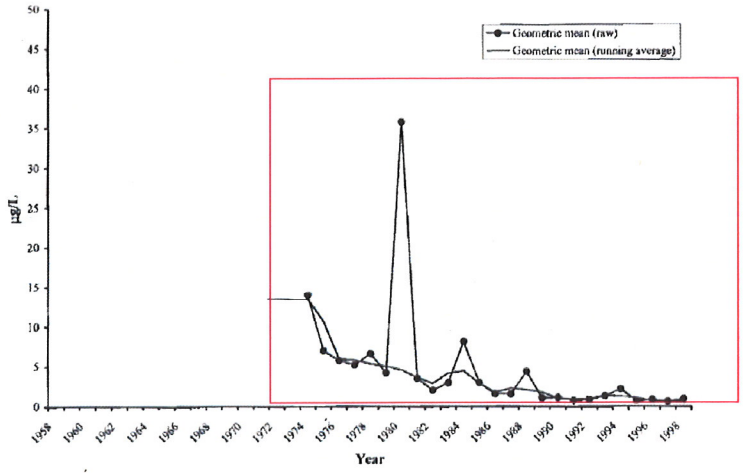
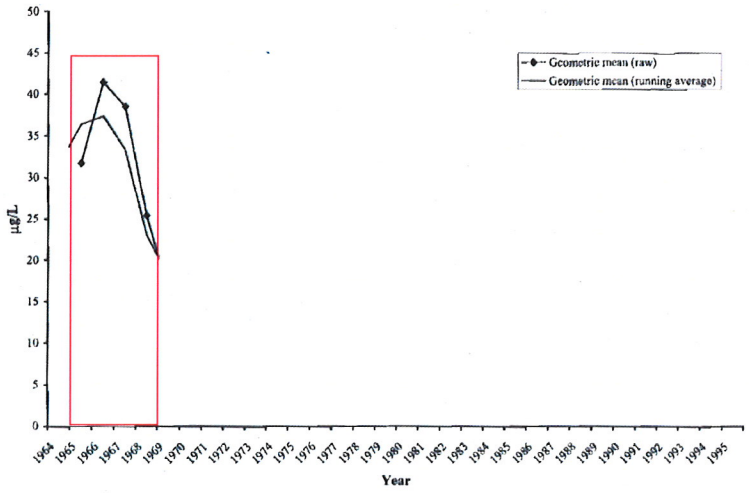


Figure 13: Lab Technicians - Leverkusen



While Worker A's initial exposure in the Kiln 1 area was short-term, high intensity, the majority of his exposure in the laboratory was long-term, low exposure. His cumulative exposure is a single value that would not reflect the changing intensity and duration of his different exposures. Conversely, the Final Four Plant Report cohort could also include a worker who worked in the Saturation plant in Uerdingen from 1964 to 1969, only 5 years. As shown in Figure 6 of the Final Four Plant Report (CX 1 at 129), this worker in the Saturation plant during that time period would have experienced high concentrations of hexavalent chromium, albeit during a short period of time:

Figure 6: Saturation - Uerdingen



Nonetheless, neither the intensity nor the duration of exposure would be able to be determined from the single cumulative exposure estimate calculated for this employee.

4. EPA Utilized Inaccurate and Non-Representative Data in Calculating Average Exposure Concentrations in the Plants of the Final Four Plant Report and the Gibb Study.

In determining average exposure concentration, Dr. Cooper and EPA have relied on inaccurate data. As evidence of the difference in average air concentrations among the different plants used in the Gibb Study versus the Final Four Plant Report, EPA produced exhibit CX 98. However, at the hearing, EPA's expert, Dr. Cooper, who developed this exhibit, testified that the data she utilized to show the average concentration of hexavalent chromium in the Baltimore plant from which the cohort utilized by Dr. Gibb, actually was not from the Gibb Study, but was rather from a prior report by Braver. Tr. at 215 (Cooper). Furthermore, Dr. Gibb testified that he did not utilize the Braver data, and that that data was not representative of the hexavalent concentrations he used in his study. Tr. at 1048-1049 (Gibb). Dr. Cooper also testified that, in preparing CX 98, EPA only utilized the average personal air monitoring data for

the German plants reported in the Final Four Plant Report. Air monitoring results were only available for years 1985 through 1998 in the Leverkusen plant, when the cohort from the Leverkusen plant worked from 1958 through 1999, and the air monitoring results for the Uerdingen plant were only available from 1986 through 1994, when the cohort from this plant worked from 1964 to 1995. See Figures 1 and 2 and Table 1 of CX 1 at 105,124 and 125.

Dr. Mundt testified that the use of only this data, which represented the period of time when air concentrations had greatly reduced as evidenced by the drop in chromium concentrations in urine from those plants during those periods, substantially underestimated the average air concentrations within the plants. Tr. at 900-904 (Mundt).

As explained above, while the average air concentrations of hexavalent chromium in the various plants utilized in the Final Four Plant Report and Gibb Study are completely meaningless because both studies calculated estimated cumulative exposures for each member of the cohort and correlated that measure with incidence of lung cancer, EPA's reliance on inaccurate and partial data is, as Dr. Gibb described, disingenuous, at best. Tr. at 1052 (Gibb). The crux of EPA's argument that the Final Four Plant Report did not corroborate the findings of the Gibb Study is based on the unsupportable position that the average air concentrations in the plants utilized in the Final Four Plant Report were much lower than the average air concentrations in the plant from which the Gibb cohort came, and the duration of exposure in the Final Four Plant Report cohort was much longer than the duration of exposure in the Gibb Study. As the evidence does not support EPA's argument, it clearly fails.

D. If Elementis' Failure To Submit The Final Four Plant Report Is A Violation Of TSCA Section 8(e), The Penalty Of The Magnitude Being Sought By EPA Is Excessive And Unwarranted.

As discussed above, the evidence in this matter demonstrates that Elementis was not required to submit the Final Four Plant Report under TSCA 8(e). However, to the extent there is a determination that Elementis was required to submit the Final Four Plant Report pursuant to TCSA Section 8(e), the penalty sought by EPA under its penalty policy is excessive and unwarranted. EPA's TSCA Penalty Policy allows for adjustment to penalties calculated under the policy "as justice may require." CX 102 at 2; Tr. at 591 (Ellis). Given the facts and circumstances of this matter, justice plainly does not support the extraordinary penalty sought by EPA.

EPA's penalty policy is not law, does not have the effect of law, and is not binding on the Presiding Officer. In re Employers Ins. of Wauasau, 6 E.A.D. 735, 758 (EAB 1997); In re Capozzi, 11 E.A.D. 10, 31 (EAB 2003). Under the statute, penalties can range from zero to a maximum of $25,000 per day.[7] 15 U.S.C. § 2615(a)(1). While EPA claims that its penalty policy allows for uniform application of penalties for violations of TSCA Section 8(e), the policy does not allow for consideration of differing circumstances in actions involving violations of TSCA Section 8(e), and therefore should not be followed in this matter. Most tellingly, the calculation here fails to reflect that (1) even if reportable, the information is of so little consequence that not a single regulatory action has resulted or is contemplated based on information in the Final Four Plant Report, (2) even if reportable, the failure to report was clearly made in a good-faith belief that the information was only corroborative and not new; and (3) even if mistaken, the

[7] The Federal Civil Penalties Inflation Adjustment Act provides that EPA adjust penalties to account for inflation.

conclusion that the Final Four Plant Report is not exempted was a reasonable one, i.e. this presents, at best for the Agency, an exceedingly close case by which it has barely established a violation and it would be unfair to treat this case on equal-footing with more significant and obvious violations. As to these argument, Elementis offers the following additional observations.

First, it is undisputed that EPA knew about the Gibb Study and that the Gibb Study identified the risk posed by cumulative exposure to hexavalent chromium much lower than the Final Four Plant Report. Thus, as Dr. Gibb testified, the Final Four Plant Report did not add anything to the knowledge base about the risks associated with exposure to hexavalent chromium. Tr. at 1041-1042 (Gibb). In fact, EPA's witness, Dr. Cooper, testified that EPA has not updated its risk information on hexavalent chromium since it received the Final Four Plant Report. Tr. at 259 (Cooper). Additionally, OSHA, in the preamble to the 2006 Final Rule setting a new Permissible Exposure Limit for hexavalent chromium stated that the quantitative analysis of the Final Four Plant Report would not provide any additional information on risk from low level exposures to hexavalent chromium. CX 76 at 81. Thus, the actual value of the Final Four Plant Report to EPA is clearly not significant.

Second, there was no evidence presented indicating Elementis intended to hide the Final Four Plant Report from EPA or anyone else. Dr. Barnhart testified that he was aware that Dr. Mundt was presenting the results of the Final Four Plant Report at a large, international meeting of epidemiologists in Barcelona prior to providing the Final Four Plant Report to Elementis, which Dr. Mundt did. Tr. at 986-987 (Barnhart); Tr. at 703-706 (Mundt). Dr. Barnhart decided against providing the Final Four Plant Report to EPA

pursuant to a good faith interpretation of the statute and EPA's policy and guidance documents, and there is no evidence to the contrary.

Third, EPA employee Tony Ellis testified that EPA had not received the Final Four Plant Report from either of the two other chromium chemical manufacturers and distributors, Occidental Chemical Company and Bayer AG, who received the Final Four Plant Report in addition to Elementis. Tr. at 618-619 (Ellis). Mr. Ellis also testified that EPA has not pursued enforcement against either Occidental or Bayer. Tr. at 618-619.

Finally, it is clear that of all witnesses presented, the one with the broadest Agency experience and the deepest experience in assessing hexavalent chromium risks was Dr. Gibb. Thus, it bears emphasizing that he regarded the Final Four Plant Study as presenting no significant new risk information. This evidences that, if a violation occurred at all, it must have been by the barest of margins and in a circumstance where, at best for EPA, reasonable scientific and regulatory minds might disagree. It is similarly clear that EPA's own guidance and regulations, limited as they are, lend comfort to the conclusion that reporting would not have been required here.

Thus, these factors all weigh against the excessive and unreasonable penalty being sought by EPA. To the contrary, they all clearly indicate that, if any penalty is appropriate, it should be nominal. There is no need to punish Elementis, as the uncontroverted evidence is that its actions were based on a good faith interpretation of a one-sentence provision with little guidance and precedence on which it could have relied, and there was no loss to the useful knowledge base of the risks associated with hexavalent chromium.

V. CONCLUSION

WHEREFORE, Elementis respectfully requests that the Presiding Officer issue an order that Elementis did not violate Section 8(e) of TSCA by not immediately submitting the Final Four Plant Report to EPA.

Respectfully submitted,

Date: April 16, 2012

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Elementis Chromium Inc.

CERTIFICATE OF SERVICE

I, Ronald J. Tenpas, hereby certify that on April 16, 2012, I served a copy of *Initial Post-Hearing Brief of Respondent Elementis Chromium Inc.* and *Respondent's Proposed Findings of Fact, Proposed Conclusions of Law and Proposed Order*, via E-mail and Federal Express on the following:

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U.S. Environmental Protection Agency
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Denver, CO 80202-1129

Erin K. Saylor, Esquire
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Office of Civil Enforcement
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W. (MC 2249A)
Washington, DC 20460-0001

Ronald J. Tenpas

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

IN THE MATTER OF:	)	
	)	Docket No. TSCA-HQ-2010-5022
	)	
Elementis Chromium Inc.	)	
f/k/a Elementis Chromium, L.P.,	)	
	)	
	)	
Respondent.	)	
	)	

RESPONDENT'S PROPOSED FINDINGS OF FACT, PROPOSED CONCLUSIONS OF LAW AND PROPOSED ORDER

Pursuant to Rule 22.26 of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination of Permits, 40 C.F.R. § 22.26, and the Presiding Officer's December 12, 2011 Post-Hearing Scheduling Order, Respondent, Elementis Chromium Inc. ("Elementis" or "Respondent") respectfully submits the following Proposed Findings of Fact, Proposed Conclusions of Law and Proposed Order.

I. PROPOSED FINDINGS OF FACT

1. Elementis Chromium Inc. ("Respondent") is a manufacturer and distributor of chemical substances, including chromic acid, chromic oxide, and sodium dichromate.

2. Respondent and its predecessors have been manufacturing and distributing chromium chemicals for more than 35 years.

3. From at least 1984 to 2003, Respondent was a member of the Industrial Health Foundation (the "IHF"), an industry-based organization.

4. From at least 1984 to 2003, Respondent was a member of the IHF's Chromium Chemicals Health and Environmental Committee (the "Chromium Committee").

5. From 1984 until 2003 when IHF was dissolved in bankruptcy, Dr. Barnhart, who was Vice President – Technical for Respondent, served as a representative of Respondent on the IHF Chromium Chemicals Health and Environmental Committee.

6. As of 1998, in addition to Respondent's representatives, representatives of two other companies, Bayer AG ("Bayer") and Occidental Chemical Corporation ("Occidental"), were members of the Chromium Committee.

7. In or about 1998, the Chromium Committee entered into an agreement with Applied Epidemiology Inc. which called for Applied Epidemiology to conduct an epidemiology study (the Four Plant Study") involving two chromium chemicals manufacturing plants located in the United States (Castle Hayne, North Carolina, which was owned by Occidental, and Corpus Christi, Texas, which was owned by Respondent), two chromium chemicals manufacturing plants located in Germany owned by Bayer (Leverkusen and Uerdingen, Germany) and one chromium chemicals manufacturing plant in the United Kingdom owned by Respondent (Eaglescliffe, England).

8. In 1999, the Eaglescliffe, England chromium chemicals manufacturing plant was eliminated from the epidemiology study because it became apparent that the data from that plant would not be compiled in time to be included in the study.

9. The Four Plant Study was designed to be a mortality study of employees who had worked in the plants for at least one year, and who had started working after each of the plants had implemented various production changes designed to reduce exposures to hexavalent chromium.

10. Dr. Kenneth Mundt was a principal of Applied Epidemiology and the lead epidemiologist for the Four Plant Study.

11. Each cohort member was followed for vital status as of December 31, 1998.

12. In early 2002, Dr. Mundt submitted a draft of Applied Epidemiology's report on the Four Plant Study to the Chromium Committee for review and comment.

13. Dr. Barnhart received the draft in early 2002.

14. In reviewing the draft, and through prior conversations he had had with Dr. Mundt, Dr. Barnhart realized that the Four Plant Study identified an elevated risk of lung cancer from cumulative exposure to hexavalent chromium for the highest cumulative exposure quartile ($\geq$ 200 µg/L-years) using standardized mortality ratio analysis.

15. This finding was the only finding in the draft report that showed any substantial risk associated with hexavalent chromium.

16. Through standard data conversion methods, Dr. Barnhart compared the mean of the cumulative exposure quartile at which the Four Plant Study had found an elevated risk with the findings of a study conducted by Dr. Herman Gibb and others which had been published in 2000 in the American Journal of Industrial Medicine (the "Gibb Study").

17. The Gibb Study was an epidemiology study of chromate workers at a chromium chemicals manufacturing facility in Baltimore.

18. Like the Four Plant Study, the Gibb Study found an elevated risk of lung cancer for workers exposed to hexavalent chromium.

19. The Gibb Study found a statistically significant increased risk of lung cancer in workers who had much lower cumulative exposures or doses of hexavalent chromium than that found by the Four Plant Study.

20. Based on his comparison of the Gibb Study and the draft report on the Four Plant Study, Dr. Barnhart determined that the Four Plant Study did not provide any new information regarding the substantial risk associated with hexavalent chromium.

21. Dr. Barnhart also knew that Dr. Gibb was employed by EPA at the time the Gibb Study was published and that EPA had funded the Gibb Study.

22. Because the Four Plant Study did not identify a substantial risk associated with hexavalent chromium not already identified by the Gibb Study, and because he knew that EPA had the Gibb Study, Dr. Barnhart did not report the finding of the Four Plant Study regarding the increased risk of lung cancer in the highest cumulative exposure quartile to EPA.

23. On October 8, 2002, Dr. Mundt emailed the "final" copy of the report entitled *Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958 – 1998: Final Report* ("Final Four Plant Report") dated September 27, 2002 to the IHF.

24. Marianne Kaschak of the IHF e-mailed the Final Four Plant Report to Dr. Barnhart on October 8, 2002.

25. Dr. Barnhart reviewed the Final Four Plant Report and did not identify any significant changes to the findings from the draft he received in early 2002.

26. Neither Occidental nor Bayer provided the Final Four Plant Report to EPA.

27. Respondent provided the Final Four Plant Report to EPA on November 17, 2008 in response to a subpoena.

II. PROPOSED CONCLUSIONS OF LAW

1. Respondent manufactures and distributes in commerce hexavalent chromium, a chemical substance.

2. When Respondent received the Final Four Plant Report in October 2002, it obtained information which reasonably supports the conclusion that exposure to hexavalent chromium presents a substantial risk of injury to health or the environment.

3. Respondent was not required by Section 8(e) of the Toxic Substances Control Act, 15 U.S.C. § 2607(e), to immediately inform the Administrator of such information because Respondent had actual knowledge that the Administrator had been adequately informed of such information.

III PROPOSED ORDER

After hearing and consideration of the evidence, it is found that Respondent did not violate Section 8(e) of the Toxic Substances Control Act, 15 U.S.C. § 2607(e), by failing to immediately provide the Administrator with the report entitled *Collaborative Cohort Mortality Study of Four Chromate Production Facilities, 1958 – 1998: Final Report* dated September 27, 2002. Accordingly, the Complaint is hereby dismissed.

Pursuant to 40 C.F.R. § 22.27(c), this Initial Decision shall become a final order 45 days after its service upon the parties, unless a party moves to reopen the hearing under 40 C.F.R. § 22.28, an appeal is taken to the Environmental Appeals Board within 30 days of service of this Initial Decision pursuant to 40 C.F.R. § 22.30(a), or the Board elects to review this Initial Decision, upon its own initiative, as provided in 40 C.F.R. § 22.30(b).

Respectfully submitted,

Date: April 16, 2012

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